

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*

Case No. 1:18-OP-45090

*The County of Cuyahoga v. Purdue Pharma
L.P., et al.*

Case No. 17-OP-45004

MDL NO. 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO
EXCLUDE THE TESTIMONY OF DAVID A. KESSLER, M.D. AND MATTHEW
PERRI, III BS PHARM, Ph.D., RPh**

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INTRODUCTION

Despite conceding that Perri's "*principles of marketing*" are "not a methodology," Opp. at 14, Plaintiffs nonetheless insist Perri's opinions are admissible because he used a "case study methodology grounded in *marketing principles*." Opp. at 13 (emphasis added). This circular argument entirely misses the point of the *Daubert* challenge. It is impossible to replicate or test Perri's purported methodology. Any standards used by Perri exist only in his mind, or collapse back into the "principles of marketing" that the Plaintiffs have disclaimed as a methodology. Perri's opinions are nothing more than his subjective conclusions, and merely invoking the word "methodology" does not change this. For this reason alone, the Court should exclude Perri's opinions in their entirety.

Perri's opinion that Defendants "failed to adhere to industry standards" also should be excluded because it does not "fit" the facts and law of the case. Plaintiffs' lawyers instructed Perri to assume all Defendants' marketing was false or misleading. This absolutist assumption includes within its sweep marketing claims consistent with FDA-approved indications, such as the FDA approval of certain medications to treat chronic non-cancer pain—claims the Plaintiffs disavowed to survive a motion to dismiss. In other briefs, Defendants demonstrate that this counterfactual and improper assumption is the quicksand on which Plaintiffs' causation theories are based. For this *Daubert* challenge, it suffices to note that Perri accepts this assumption as true, so his opinions must be excluded because they lack "fit."

Kessler's and Perri's improper factual narratives and speculative opinions about Defendants' states of mind violate Federal Rule of Evidence 702 and *Daubert*, so they also should be excluded. Of course, experts can *rely on* documents in forming their opinions, but Plaintiffs cannot use Kessler and Perri to present factual summations under the guise of expert testimony.

Likewise, while experts can present facts from which the *jury* can infer intent or knowledge, the proffered testimony goes too far by presenting “expert” mind-reading. Kessler’s legal opinions similarly cross the line. His previously undisclosed opinions about Noramco are also inadmissible. Finally, Plaintiffs have not shown that Kessler is qualified to opine on marketing given his lack of relevant education and regulatory experience.¹

ARGUMENT

I. THE COURT SHOULD EXCLUDE PERRI’S OPINIONS IN THEIR ENTIRETY.

A. Perri lacks a reliable methodology.

Perri relies on vague, unarticulated “*principles of marketing*” to reach his conclusions. *See* Perri Rpt. ¶ 14 (emphasis added); *see also* Mem at 6-7. Plaintiffs now concede “the principles are not a methodology,” Opp. at 16, but defend Perri’s opinion as being based on “a case study methodology grounded in *marketing principles*.” Opp. at 13. That is no better. Expert testimony “must be grounded in an accepted body of learning or experience . . . and the expert must explain how the conclusion is so grounded.” FED. R. EVID. 702 advisory committee note (2000); *see also Vinel v. Union Twp.*, No. 1:16-CV-930, 2018 WL 7080037, at *7 (S.D. Ohio Apr. 13, 2018) (excluding expert who “fail[ed] to sufficiently explain the methodology supporting [his] . . . conclusion.”). Perri’s opinion fails this test.

Plaintiffs claim Perri applied his “case study methodology” to “multiple data points, documents and testimony,” Opp. at 14-15, but say nothing about how that methodology works or how Perri weighed or evaluated these data and documents. A reliable methodology would make

¹ Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are, respectively, an Israeli corporation, an Irish holding company, and an Irish company. They are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion, and, thus, they do not waive, and expressly preserve their personal jurisdiction challenges.

Perri's analysis clear so that it could be tested and replicated. Tellingly, Plaintiffs do not cite a single case that allowed a "case study methodology." Even more rigorous scientific case studies "reflect[] only reported data, not scientific methodology." *Rose v. Matrixx Initiatives, Inc.*, No. 07-2404-JPMTMP, 2009 WL 902311, at *15 (W.D. Tenn. Mar. 31, 2009) (excluding opinion that relied on case study).

It is not enough for an expert simply to present a conclusion and claim to have derived it from the data and documents. *E.g., Balimunkwe v. Bank of America*, No. 1:14-CV-327, 2015 WL 5167632, at *14 (S.D. Ohio Sept. 3, 2015), *rpt. & rec. adopted*, 2015 WL 5836975 (S.D. Ohio Oct. 2, 2015) (rejecting expert who did "not explain *how* he used . . . various instruments to compare . . . samples and verify patterns"). Indeed, such an approach is especially unreliable because it is "extremely discretionary." *See id.* Perri's opinions, which present subjective conclusions without any meaningful methodology, are unreliable.

B. Perri bases his core opinion on a counterfactual and improper assumption.

Perri's opinion that "Defendants' marketing failed to adhere to industry standards," Perri Rpt. at 8, does not "fit" the case because it is based on the improper and counterfactual assumption that *all* of Defendants' advertising was false or misleading. *See* Mem. at 6-9. Plaintiffs' response that this was "only one of [his] seven opinions," Opp. at 17, ignores the problem. The alleged breach of industry standards is the *only* opinion that charges the Manufacturers with any wrongdoing and, thus, is the most relevant to Plaintiffs' theory of the case.

Similarly, Plaintiffs argue that Perri's absolutist assumption was "just one data point" he considered. *Id.* Perri does not explain how he weighed this "one data point," but the counterfactual assumption that all marketing was false and misleading must have been a significant factor—if not the only factor—driving Perri's conclusion that the marketing was improper.

II. EXPERT NARRATIVES ARE IMPROPER BECAUSE A JURY DETERMINES FACTS AT ISSUE, INTERPRETS NON-TECHNICAL EVIDENCE, AND APPLIES THE LAW TO THOSE FACTS.

Kessler and Perri's opinions, which merely summarize marketing testimony and documents as a lawyer would do in a closing argument, are improper expert opinions that should be excluded as unhelpful to the trier of fact. Plaintiffs cannot use experts as a mouthpiece to present their theory of the case. *See* Mem. at 11-12 (collecting cases). This Court has excluded just such testimony. *In re Gadolinium-Based Contrast Agents Prod. Liab. Litig.*, No. 1:08 GD 50000, 2010 WL 1796334, at *13 (N.D. Ohio May 4, 2010), *modified on reconsideration*, No. 1:08 GD 50000, 2010 WL 5173568 (N.D. Ohio June 18, 2010), *aff'd sub nom. Decker v. GE Healthcare Inc.*, 770 F.3d 378 (6th Cir. 2014). Several of Plaintiffs' cited cases held the same. *In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641-PHX DGC, 2017 WL 6523833, at *2 (D. Ariz. Dec. 21, 2017) (excluding expert's "lengthy discussion of documents, depositions, events, and other facts" supporting Plaintiffs' case); *Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) ("To be clear, this court will not permit either [expert] to merely recite or summarize documents."); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (holding "to the extent" that "selective quotation from internal Merck documents, regulatory filings, and the deposition testimony" are admissible, they "should be presented to the jury directly").

Plaintiffs argue that experts are allowed to rely on and discuss documents that form the basis of their opinions. Opp. at 4-5. That is beside the point. An expert cannot be used as a mere document delivery vehicle. As one of Plaintiffs' cited cases explains, "an expert may testify about his or her review of internal corporate documents *solely for the purpose of explaining the basis for his or her opinions.*" *Sanchez v. Bos. Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *4 (S.D.W. Va. Sept. 29, 2014). The court in *Sanchez* excluded the expert because his opinion

went further, and “[m]uch of [his] expert report [was] a narrative review of corporate documents.” *Id.* at *31. Here too, Kessler and Perri provide a narrative review of Defendants’ documents.

Recognizing the narrative nature of Kessler’s and Perri’s opinions, Plaintiffs argue that the Court should exercise its discretion to allow the testimony. *Opp.* at 5-6 (citation omitted). But courts do not have discretion to admit the inadmissible. An expert’s recitation of self-explanatory facts or documents is inadmissible under Federal Rule of Evidence 702(a). *United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254, at *11 (N.D. Ala. Dec. 4, 2014), *vacated & aff’d for interlocutory app.*, 2014 WL 12593996 (N.D. Ala. Dec. 19, 2014) (holding that Perri may not “merely recite[] the documentary evidence and testimony . . . regarding AseraCare’s marketing and business practices” and then offer unexplained conclusions he drew from them). Plaintiffs’ facile response that *AseraCare* did not use the word “narrative,” *Opp.* at 19, is an argument of form over substance and does not move the bar here.

Finally, Plaintiffs cite cases that allowed in-depth expert testimony about the FDA’s history or processes because the facts were too “complicated” for the jury to understand otherwise. *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, No. 2:12-CV-07263, 2016 WL 4538621, at *8 (E.D. Pa. Aug. 31, 2016) (cited in *Opp.* at 6). That logic does not apply here, as shown by the fact that Kessler and Perri explain almost none of the snippets they cite. Rather, they simply excerpt, repackage, and regurgitate marketing documents. *See, e.g.*, Perri Rept. at 86-128 (including table of documents with a quote or summary describing each). Experts cannot “regurgitat[e] . . . known facts without any additional insight into how those facts pertain to this case.” *Id.*; *see also Johnson*, 2012 WL 1204081, at *3. These opinions are inadmissible.

III. EXPERTS CANNOT PRESENT INFERENTIAL OPINIONS ABOUT KNOWLEDGE, INTENT, OR STATES OF MIND.

An expert “cannot be permitted to speculate as to the intent or state of mind of [a

manufacturer or] the FDA.” *See, e.g., Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221, at *3 (W.D. Okla. Feb. 4, 2013) (limiting Kessler’s testimony); *see also* Mem. at 12-15 (collecting cases). This Court excluded just such testimony in *In re Gadolinium-Based Contrast Agents*, 2010 WL 1796334, at *13. So did the courts in four of the cases cited by Plaintiffs. *In re Bard IVC Filters*, 2017 WL 6523833, at *4; *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 294-96 (E.D. Pa. 2016); *Sanchez*, 2014 WL 4851989, at *4; *In re Fosamax*, 645 F. Supp. 2d at 192.

Plaintiffs cite other decisions for the proposition that an expert may “testify about facts *from which the jury can infer intent*.” *Wells*, 2013 WL 7208221, at *2 (emphasis added); *accord DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998); *In re Tylenol*, 181 F. Supp. 3d at 294-96 & n.29; *see also* Opp. at 7-8, 10 (quoting the same language). In each of these cases, however, the courts specifically *prohibited* experts who offered their *own* opinions about intent. Similarly, Plaintiffs cite decisions allowing testimony about information “available,” *In re Flonase Antitrust Litig.*, 884 F. Supp. 2d 184, 192 (E.D. Pa. 2012), or within the “possession” of the defendant. *Stults v. Int’l Flavors & Fragrances, Inc.*, No. C 11-4077-MWB, 2014 WL 12603223, at *3 (N.D. Iowa July 18, 2014); *accord In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 479-80 (S.D.N.Y. 2016). These decisions allowed discussions of *facts* from which a jury could draw its own inferences, *not* expert opinions as to intent or state of mind. Finally, some cases have permitted Kessler’s testimony only because he did *not* offer opinions about states of mind. *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *12 (S.D. Ill. Dec. 16, 2011) (“Dr. Kessler . . . [does] not intend to testify about the intent or motive of Bayer’s personnel.”); *see also In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prods. Liab. Litig.*, 2016 WL 4039329, at *5-6 (E.D.

Pa. July 28, 2016) (similar); *In re Testosterone Replacement Therapy Products Liability Litigation*, No. 14 C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) (permitting Kessler to opine about FDA's regulatory approval of "intended uses" for a prescription medication).

In any event, Plaintiffs apparently agree that allowing Kessler and Perri to opine on intent would be improper. *See* Opp. at 13 ("Perri's opinion is not an opinion about intent, but rather about marketing theory."); *id.* at 11 (Kessler will not offer "speculation about intent"). The Court should hold Plaintiffs to that concession and rule that Kessler and Perri **cannot** offer opinions about the FDA's or Defendants' intent or states of mind.

IV. KESSLER CANNOT OFFER LEGAL OPINIONS, AND PLAINTIFFS FAIL TO IDENTIFY KESSLER'S RELEVANT MARKETING EXPERTISE OR WHERE HE DISCLOSED HIS OPINIONS ABOUT NORAMCO.

Expert witnesses are not allowed to offer legal opinions. *Shahid v. City of Detroit*, 889 F.2d 1543, 1547 (6th Cir. 1989); *United States v. Zipkin*, 729 F.2d 384, 387 (6th Cir. 1984). But the purpose of Kessler's testimony is exactly that: to interpret FDA regulations, and to opine that Defendants violated them. *E.g.*, Kessler Rpt. at 14-28, ¶¶ 99, 170; Opp. at 2 (describing Kessler's conclusion that Defendants "departed from FDA standards").

Plaintiffs suggest an opinion is a legal conclusion when "the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular." Opp. at 22 (quoting *In re C.R. Bard*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013), *on reconsideration in part* (June 14, 2013)). Kessler's testimony qualifies as a legal conclusion under that standard. The court in *C.R. Bard* barred Kessler from opining that a medication was "not reasonably safe" or that the defendant "failed to warn" because those were legal terms of art. *Id.* Kessler's opinions here that certain statements were "misleading" or "unsubstantiated," or that products were "falsely marketed" are inadmissible for the same reason.

Several of the other cases Plaintiffs cite, Opp. at 22-23, only allowed the expert to provide

background about FDA regulations and operations, not the defendant's compliance. *E.g., Georges v. Novartis Pharm. Corp.*, No. CV 06-5207 SJO VBKX, 2012 WL 9064768, at *9 (C.D. Cal. Nov. 2, 2012) ("Dr. Parisian is not permitted to offer legal conclusions on any topic, including whether Defendant was in regulatory compliance . . ."). Finally, Kessler may not opine as to matters of state law, or the interplay between state law and Defendants' alleged FDA violations. *E.g., Drake v. Allergan, Inc.*, No. 2:13-CV-234, 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014). Thus, the Court should prevent Kessler from offering such testimony in this case.

In addition, Kessler is not a qualified expert on pharmaceutical marketing. *See* Mem. at 5 (describing lack of expertise). Plaintiffs' brief does not respond to this point, apparently conceding that Kessler may not testify regarding marketing.

Finally, at his deposition Kessler offered a previously undisclosed, inadmissible opinion relating to Noramco—a defendant Plaintiffs moved to sever.² Plaintiffs claim this opinion was disclosed but, tellingly, do not cite any part of his report that does so. Instead, they claim that this opinion is supported by *documents* Kessler cited in his report for other purposes. This does not meet the duty to disclose "a complete statement of all opinions the witness will express and the basis and reasons for them." FED. R. CIV. P. 26(a)(2)(B)(i). The undisclosed opinion must be excluded.

CONCLUSION

For the foregoing reasons, and those set forth in Defendant's opening memorandum, the Manufacturers request that the Court exclude the testimony of Perri and Kessler.

² Plaintiffs have not responded to Noramco's motion for summary judgment, claiming to need more discovery, having previously opted not to seek discovery from Noramco. *See* Noramco's Opp. to Mot. to Pls.' Mot. to Sever (Dkt. 2141).

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Lindsey B. Cohan, hereby certify that the foregoing document as served via the Court's ECF system to all counsel of record.

/s/ Lindsey B. Cohan

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